**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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**IN RE:**

**FOSAMAX PRODUCTS LIABILITY LITIGATION**

**MASTER FILE:**
**NO. 1:06-MD-01789-JFK-JCF**

**This document relates only to:**
***Shirley Boles v. Merck & Co., Inc.***
**Case No.: 1:06-CV-09455-JFK**

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**PLAINTIFF SHIRLEY BOLES' MEMORANDUM IN OPPOSITION TO MERCK'S F.R.Civ.P. 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW**

COMES NOW SHIRLEY BOLES, Plaintiff herein, and presents the following memorandum of authorities in opposition to Defendant's Rule 50(b) Motion for Judgment as a Matter of Law. While Plaintiff is presenting this memorandum in opposition to the motion, she relies upon the entirety of the trial record before the Court, and this Court should accordingly deny Defendant's Motion for Judgment as a Matter of Law. This Court has previously denied Defendant's efforts to dismiss this case, couched as both a pretrial Rule 56 motion for summary judgment, and two Rule 50(a) directed verdict motions made during the trial of the case. Defendant presents no new evidence or intervening authority which would demonstrate to this Court that its prior rulings were incorrect. Therefore, for the reasons previously stated, as well as the law of the case doctrine, this Court should deny Defndant's Rule 50(b) Motion for Judgment as a Matter of Law.

## I. THIS COURT SHOULD NOT DEPART FROM ITS PREVIOUSLY DECIDED RULINGS.

Defendant brings to this Court its' fourth motion for judgment as a matter of law. While this is the first Rule 50(b) motion Defendant has filed, Defendant's Rule 50(b) motion must be reviewed under the same standard that the Court applied to its motions under Rule 56 and Rule 50(a). *This Is Me, Inc. v. Taylor*, 157 F.3d 139, 142 (2nd Cir. 1998; *see also* 9B Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE § 2537, at n.35 (2009). Thus, under Rule 50(b), the Court must draw all reasonable inference in favor of the non-movant. *Alfaro v. Wal-Mart Stores,* Inc., 210 F.3d 111, 114 (2nd Cir. 2000); *see also Chaney v. City of Orlando*, 483 F.3d 1221, 1228 (11th Cir. 2007) ("The fact that Rule 50(b) uses the word 'renew[ed]' makes clear that a Rule 50(b) motion should be decided in the same way it would have been decided prior to the jury's verdict, and that the jury's particular findings are not germane to the legal analysis"). Accordingly, as this Court has already conducted the requisite legal analysis and ruled, this Court should deny Defendant's motion outright under the law of the case doctrine, because Defendant's motion does not establish that the Court's prior rulings were "clear error" or resulted in a "manifest injustice".

"As most commonly defined, the [law of the case] doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983). The law of the case doctrine is well established and followed in the Second Circuit:

> The law of the case doctrine has two branches. The first requires a trial court to follow an appellate court's previous ruling on an issue in the same case. The second and more flexible branch is implicated when a court reconsiders its own ruling on an issue in the absence of an intervening

> ruling on the issue by a higher court. It holds that when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case, unless cogent and compelling reasons militate otherwise.

*United States v. Quintieri*, 306 F.3d 1217, 1225 (2nd Cir. 2002) (quot. and cit. omit.)

Absent a change in controlling law or new evidence, where a court cannot find that manifest injustice will result from adhering to its prior order, the law of the case doctrine permits departure only if the court's prior ruling is "clear error". *Johnson v. Holder*, 564 F.2d 95, 99-100 (2nd Cir. 2009); *see also Washington Nat'l Life Ins. Co. of New York v. Morgan Stanley & Co., Inc.*, 974 F.Supp. 214, 218-19 (S.D.N.Y. 1997) (quot. and cit. omit.) (Lowe, J.) ("Although the doctrine does not restrict a court's authority to revisit a previously decided issue, courts should be loathe to do so in the absence of extraordinary circumstances, such as where the initial decision was clearly erroneous and would work a manifest injustice").

This Court has previously ruled upon Defendant's several motions for judgment as a matter of law. In its prior ruling, granting in part and denying in part Defendant's Rule 56 motion for summary judgment, this Court expressly ruled upon the issues of law presented by Defendant, finding that there was sufficient evidence from which a reasonable trier of fact could find that Defendant violated the duties owed to Plaintiff and her prescriber. In an exhaustive 42 page order, this Court carefully assessed the proffered evidence and found that there were genuine disputes as to issues of material fact which would require the trier of fact to resolve on the negligence and strict liability claims, but the Court granted Defendant's motion as to Mrs. Boles' prayer for punitive damages. (1:06-md-01789, Doc. 756.)

During the trial of the case, at the conclusion of Plaintiff's evidence, Plaintiff's counsel was forthright with the Court and expressly indicated to the Court that the Court's prior ruling on the punitive damages prayer likely controlled the issue as to the fraudulent misrepresentation element of Plaintiff's case[1]:

> With regard to the fraudulent misrepresentation, I think in duty and candor to the Court, I do believe we opposed the motion, but we believe that that would be covered by the Court's order on partial summary judgment; because if we were to prevail on a fraudulent misrepresentation claim, then we'd be entitled to punitive damages.
>
> So we oppose the motion, but believe that the law of the case - - in all candor to the Court - - would cover that element of plaintiff's claim, which we oppose and think that the Court should reverse itself on the issue of fraud based upon the evidence that the Court has heard.

(1629:5-15[2].) Ultimately, on September 1, 2009, this Court held that the issue was decided upon by the Court in its prior summary judgment ruling and therefore Plaintiff would not be entitled to present the issue to the jury for its consideration. (2359:23-2361:2.) At the same time, however, the Court denied Defendant's renewed Rule 50(a) motion. Previously, on August 24, 2009, this Court denied Defendant's initial Rule 50(a) motion, and presented the basis for its ruling. (1630:5-1631:22.)

Accordingly, this Court has denied Defendant's application for judgment as a matter of law three times. Defendant has presented no new evidence or authority which would require this Court to conclude it previously misapprehended the law and the issues

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[1] Contrary to defense counsel's representation (at 2355:21- 2356:3 of the transcript) to the Court that Plaintiff "waived" her fraudulent misrepresentation claim, no such waiver was made. The Court ruled and Plaintiff's counsel expressly indicated that he felt duty-bound to explain to the Court the implications of the Court's prior summary judgment ruling under Florida law, relating to the fraudulent misrepresentation claim, but did not waive his opposition to the Court's ruling. The Court noted the same and indicated to Plaintiff's counsel that his client's opposition was of record and the exception conveyed. (2360:24-2361:1.)

[2] All page and line references in this brief pertain to the trial transcript, unless otherwise noted.

before it and, therefore, depart from its prior rulings. In light of the countless rulings on scientific and evidentiary issues made in this case by this Court, after tireless research by the Court and its staff, the law of the case doctrine should preserve this Court's prior rulings. Otherwise, when this case is retried, Defendant will be looking to get second, third, and fourth bites at the apples and wasting judicial resources, moving this Court to reverse itself on its prior rulings.

The law of the case doctrine is "driven by fairness to the parties, judicial economy, and the societal interest in finality." *United States v. Carr*, 557 F.3d 93, 102 (2nd Cir. 2009). The parties to the case *sub judice* have a need to know that the prior rulings still apply *per force* and the Court should not be prevailed upon to change its prior rulings. This Court should deny Defendant's Rule 50(b) motion in its entirety.

## II. MERCK FAILED TO ADEQUATELY INFORM MRS. BOLES' PRESCRIBING PHYSICIAN OF THE RISKS AND BENEFITS ASSOCIATED WITH FOSAMAX AND THEREBY PROXIMATELY CAUSED HER INJURY.

### A. Defendant's Duty to Adequately Warn and Instruct Began Before October 2003.

Defendant argues that the evidence presented to the jury was not sufficient to implicate its duty to adequately warn and instruct physicians concerning Fosamax about the risk of ONJ and the limitations to the efficacy of Fosamax. This Court expressly considered Merck's Rule 50(a) motion at the close of Plaintiff's evidence, and denied the motion: "Here, the jury could conclude, I believe, that Merck's failure to provide all information regarding the risks and benefits associated with Fosamax was a proximate cause of the plaintiff's injury. Further, a jury might reasonably conclude that the risks of Fosamax outweigh its benefits when used for prevention rather than treatment of

osteoporosis." (1630:21-1631:1.) This Court properly considered the evidence presented to the jury in reaching that decision, such as the following:

| WITNESS | TESTIMONY |
|---|---|
| Parisian | The manufacturer bears responsibility, at all times, to ensure that its prescription drug's label is adequate. (1085:4-7.) |
| Parisian | In order for a warning to be adequate, it must contain adequate instructions regarding efficacy. (1101:21-23) |
| Parisian | Definition of osteoporosis provided in the 1997 Fosamax label was -2.0 standard deviations below the mean, when the WHO definition was actually a T-score of 2.5. (1093:6-24) |
| Dr. Baran (Merck) | Merck has no study showing fracture risk reduction conveyed by Fosamax for osteopenic patients. (575:18-25) |
| Dr. Santora (Merck) | There is no evidence that Fosamax prevents fractures in women without osteoporosis. (300:18-301:7) |
| Dr. Bilezikian | There is no evidence that Fosamax prevents fractures in women without osteoporosis. (2436:18-22, 2247:5-12; 2248:15-17) |
| Parisian | During the time Mrs. Boles was on the drug, Fosamax had no evidence of fracture reduction benefit in women who were osteopenic. (1236:24-1237:6). |
| Parisian | The 1999 label does not contain information about the limited duration of fracture reduction efficacy for osteoporotic patients and the lack of fracture reduction efficacy for osteopenic patients. (1099:9-16, 1105:23-1106:12, 1242:16-24) |
| Parisian | Merck overstated the benefits of Fosamax. (1132:1015, 1242:16-24) |
| Parisian | During the times relevant to the case before the jury, the label for Fosamax did not reflect that the drug had no fracture benefit for osteopenic women or that that it carried a risk of ONJ. Therefore, physicians were unable to make an adequate risk-benefit assessment for their Fosamax patients. (1242:7-1244:9) |

Defendant's efforts to achieve judgment as a matter of law, both during the trial of the case and to the present time, are undermined by the applicable standards of care relating to pharmacovigilance:

| WITNESS | TESTIMONY |
|---|---|
| Bold (Merck) | A single adverse event report or a very rare adverse event can constitute a safety signal. (775:4-7) When you look at these adverse events, you look for similarities among symptoms. (779:20-780:1) |
| Exh. 1.0922B<br>Exh. 1.0970<br>Exh. 1.2364<br>Exh. 1.2367<br>Exh. 1.2640 | Merck had multiple adverse events of jaw bone problems with symptoms like ONJ prior to October 2003. |
| Bold (Merck) | Merck had no written procedure to define for its pharmacovigilance employees what constitutes a safety signal. (810:19-811:25) |
| Bold (Merck) | Merck had no system in place to ensure or record that Merck's safety surveillance physicians actually reviewed Merck's internal adverse event reports. (789:23-791:5.) |

In its present Rule 50 motion, Defendant evidently chides this Court for its rulings allowing the testimony of Dr. Parisian, arguing the permitted testimony exceeded her area of expertise. However, this Court should not be dissuaded from its rulings, based as they were on one of the longest *Daubert* orders in pharmaceutical MDL history. Furthermore, Dr. Parisian's testimony is consistent with FDA pharmacovigilance guidelines (and Dr. Bold's testimony) which says that even one case of a rare adverse event reported to a pharmaceutical manufacturer can constitute a signal, triggering the duty to warn.

As the law proviees, under the changes-being-effected provision of 21 C.F.R.§ 314.70(c)(6)(iii), Merck had the ability and duty to unilaterally implement a

strengthening of its warnings, precaution, or adverse reaction section of its label without waiting for prior FDA request or approval. *Wyeth v. Levine*, 129 S.Ct. 1187, 1196-98 (2009).

Under either the FDA's, Merck's or Dr. Parisian's understanding of pharmacovigilance principles, one rare adverse event reports can constitute a signal, thus triggering the duty to investigate and warn. This is consistent with federal case law on the topic, as well. Merck's adverse event reports are "highly probative" for the purpose of showing that Merck had notice of the adverse reactions and could have given a warning about ONJ. *See Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1385–86 (4th Cir. 1995). *See also Golod v. LaRoche*, 964 F. Supp. 841, 855–56 (S.D.N.Y. 1997) (Sweet, J.) (adverse event reports are relevant to manufacturer's awareness of serious effects and need to conduct further research).

As it had the duty to advise physicians, accurately, of the risks and benefits of Fosamax, when Merck failed to give Dr. Mills the requisite information necessary to the risk-benefit calculus, it breached the duty and thereby could be held, by a reasonable trier of fact, to have proximately caused Shirley Boles' ONJ. This Court's prior express ruling on this matter was correctly reached and should remain as previously issued.

### B. This Court Correctly Ruled that a Reasonable Jury Could Conclude that Merck's Failure to Give Complete Risk-Benefit Information to the Intermediary Proximately Caused Mrs. Boles' Injury.

Under Florida law, the risk-benefit analysis to be performed by a doctor is by necessity a combined analysis. Defendant again attempts to have this Court depart from Florida law by segregating the two components of the risk-benefit analysis and striking one from the equation. In this case, the evidence showed that Dr. Mills had no

knowledge of the risk of ONJ, from Merck or any other source, before October 1, 2003, and that the benefits of the drug were overstated. Accordingly, this Court should not grant judgment as a matter of law.

In its Rule 50(b) motion, Defendant argues that Dr. Mills did not offer any testimony in trial on Merck's failure to warn of the risk of ONJ. Dr. Mills clearly testified that the only risk anyone from Merck ever advised him of was the risk of gastrointestinal upset. (456:13-21.) Furthermore, as stated by the Court in the Order denying summary judgment, Plaintiff's negligence and strict liability claims were only predicated, *in part*, on Merck's alleged failure to warn that Fosamax can lead to ONJ." (emphasis added) (Summ. J. Order.15). The Court even noted that Plaintiff's complaint set forth other bases for finding that the Defendant was negligent or strictly liable and it specifically cited as an example the allegation that Fosamax is an unreasonably dangerous product in that its risks exceeded its benefits. (Summ. J. Order, p. 15 n.8.) This Court issued the same reasoning and ruling in trial. (1630:21-1631:1.)

Defendant's motion focuses entirely on the failure to warn allegation in isolation rather than in the context of whether Merck provided Dr. Mills with the information necessary to perform an adequate risk-benefit analysis before prescribing the drug to Shirley Boles. Plaintiff's claims for negligence and strict liability are both predicated on the fact that the label did not adequately inform Plaintiff's prescribing physician of the risks and benefits associated with Fosamax. Because the product at issue in this case is a prescription drug, the learned intermediary doctrine applies and the defendant's duty to warn is discharged by giving an adequate warning, and in the case at hand, instruction as to its use and benefits, to the prescribing physician. *See Union Carbide Corp. v.*

*Kavanaugh*, 879 So.2d 42, 44 (Fla. 4th DCA 2004) (holding that a duty to warn can be discharged by supplying the learned intermediary with the necessary information and warnings).

The physician has "the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottoms on a knowledge of both patient and palliative." *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974) (cited with approval in *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So.2d 820 at 822 (Fla. 5th DCA 1981)). In adopting the learned intermediary doctrine, the Florida Court of Appeals, adopted the following language from the Supreme Court of Washington decision in *Terhune v. A.H. Robbins* as instructive:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.
> *Buckner*, 400 So.2d 820 at 823 (quoting *Terhune v. A.H. Robbins*, 577 P.2d 975 (1978).

It is settled law in Florida that "the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the product to meet the patient's

needs." *Baker v. Danek Medical*, 35 F.Supp.2d 875, 881 (N.D.Fla. 1998).

Dr. Mills' testimony is consistent with this well settled law wherein he stated that "if you are going to give a patient a drug, you want to be sure that it's way, way in their favor, that its going to help them rather than hurt them...and you have to weigh, is the benefit to the patient much better than the risk that you're putting them to." (457:14-24.) Dr. Mills stated very clearly that he now believes that Fosamax conferred no benefit to Ms. Boles. (487:4-6.) Dr. Mills further testified that if he had the information from Dr. Santora's testimony and the FDA statistical review regarding the lack of fracture reduction efficacy in women with T-scores like Shirley Boles (better than –2.5 standard deviations), he would not have ever prescribed Fosamax. (486:23-487:4.) Dr. Mills also indicated that had he been informed of the limited period of time for which Fosamax is efficacious in reducing fractures, he would not have prescribed it. (491:21-492:13) Dr. Mills testified that the only risk of Fosamax to his knowledge was gastrointestinal irritation. (465:13-21) Therefore, applying his own risk benefit analysis, any potential risk, be it a risk of harm Ms. Boles suffered or not, outweighs the complete lack of any benefit. This is consistent with Dr. Parisian's testimony when she told the jury that Merck's failure to warn of the risks and advise of the efficacy limitations deprived physicians of the ability to conduct a learned risk-benefit analysis. (1242:7-1244:9)

## III. PLAINTIFF HAS PRESENTED ADEQUATE EVIDENCE THAT FOSAMAX WAS DEFECTIVE.

This Court addressed the design defect accurately when it observed in the Summary Judgment Order that Plaintiff's complaint set forth other bases for finding that the Defendant was negligent or strictly liable and it specifically cited as an example the

allegation that Fosamax is an unreasonably dangerous product in that its risks exceeded its benefits. (Summ. J. Order, p. 15 n.8.) This Court issued the same reasoning and ruling in trial: "Here, the jury could conclude, I believe, that Merck's failure to provide all information regarding the risks and benefits associated with Fosamax was a proximate cause of the plaintiff's injury. Further, a jury might reasonably conclude that the risks of Fosamax outweigh its benefits when used for prevention rather than treatment of osteoporosis." (1630:21-1631:1.)

Furthermore, Defendant attempts to pigeon-hole Florida design defect law in a manner that is not reflected in Florida law. Florida law frequently intertwines the failure to warn elements into the design defect product liability claim because of the consumer-expectation theory and the risk-benefit standard. *Force v. Ford Motor Co.*, 879 So.2d 103, 106 (Fla. 5th DCA 2004). "Under the consumer-expectation theory a product is defectively designed if the plaintiff is able to demonstrate that the product did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner." *Id.; see also McConnell v. Union Carbide Corp.*, 937 So.2d 148, 151 (Fla. 4th DCA 2006). Through this manner, the plaintiff can establish that a product was "unreasonably dangerous" if it did not perform as safely as an ordinary consumer would expect. *Id.* In this case, the consumer, through the learned intermediary doctrine, is the physician. The evidence presented in this case of what was learned about the drug was through the drug label, and thus, the physician's expectation reasonably set. *See McConnell*, 937 So.2d at 151-52 (under design defect theory, consumer-expectation test properly considered absence of warning: "Without a warning, plaintiff had no way of anticipating the presence of asbestos and had every reason to

expect that the product could be safely used in the ordinary manner.") It was not disputed that there was no information at all given to the physician about osteonecrosis of the jaw nor was the physician informed of the limitations of the efficacy of Fosamax for women without osteoporosis. Accordingly, a reasonable trier of fact could deduce through the consumer-expectation theory of design defect that the product is defective. "Essentially, this test relies on deductive reasoning to conclude that the product is defective." *Force*, 879 So.2d at 106.

This also spills over into the risk-benefit standard as so much of the trial's evidence concerned the lack of benefit of Fosamax for women like Shirley Boles in comparison to the risks of using the drug.

Florida law, however, does not require the hair-splitting suggested by Defendant as pleading a specific basis for product defect, whether design or manufacturer, is not necessary to make the claim a strict liability claim under section 402A. *McConnell*, 937 So.2d at 152. Similarly, under Florida's current product liability approach, the phrase "inherently dangerous" is no longer determinative of the application of strict liability in Florida. *Radiation Tech., Inc. v. Ware Constr. Co.*, 445 So.2d 329, 331 (Fla. 1983); *Brown v. Glade & Grove Supply, Inc.*, 647 So.2d 1033, 1035 (Fla. 4th DCA 1994).

Accordingly, this Court should not reverse its prior ruling and deny Defedant's Rule 50(b) motion.

## IV. AS THIS COURT HAS PREVIOUSLY RULED, THERE IS AMPLE EVIDENCE THAT PLAINTIFF SHIRLEY BOLES' JAW INJURY MANIFESTED BEFORE OCTOBER 1, 2003.

Defendant again moves for judgment as a matter of law on the semantics of Mrs. Boles' jaw problem. As this Court ruled, there is more than ample evidence from the

record that Plaintiff Shirley Boles' jaw injury was a continuous sequence that began in 2002:

| WITNESS | TESTIMONY |
|---|---|
| Hellstein | Mrs. Boles more likely than not had stage 0 ONJ between August 2002 and September 2003. (735:11-18) |
| Hellstein, and Exh. 3.0002, p. 5 | Dr. Clark's records ofAug. 12, 2002 show a large ulceration in the area of extraction. Ulceration is the absence of epithelium and constitutes exposure. (630:9-22) |
| Hellstein and Exh. 3.0049, p. 00037. | August 16, 2002, Dr. Elwell record indicates: "This is suggestive of bony destructive scenario."(631:7-8; 631:25-632:4). Dr. Hellstein notes this again is representative of changes in the repair process of the bone. Elwell's record also reflects dead bone was removed on this same date. (632:20-23) |
| Hellstein and Exh. 3.0049, p. 00117 | August 19, 2002, pathology record from University of Florida, sampling the specifmen taken from the curretage on 8/16/02. (633:23-634:7). Specimen contained viable and non-viable bone indicating that Dr. Elwell had gotten down to viable bone. (634:11-22.) There were no osteocytes in the lacunae which indicates the bone is dead. (634:23-635:11.) Dr. Hellstein explains that with ONJ and secondary osteomyelitis, the bone's inability to heal itself or fight off infection because of something else going on that led to the osteomyelitis. (636:1-16.) |
| Hellstein and Exh. 3.0028. | Dr. Mills record fromMay 16, 2003. (Exh. 3.0028, p. 19). Pain in right central mandible is consistent with BRONJ. (639:6-13). 5/16/03 CAT scan (Ex. 3.0028, p. 49) shows a moth0eaten abnormal medullary and cortical pattern of bone. The CT describes exactly what that means and concludes it constitutes an abnormal bony change in the jaw. (639:18-640:11.) Ex. 2.0007 Hellstein's article at p. 756 the term moth-eaten is used to describe bony changes found with bisphosphonate ONJ (739:1-9). |

| | |
|---|---|
| Hellstein and Exh. 3.0049 | Dr. Elwell surgery on September 16, 2003 (Exh.. 3.0049, p. 00120). Probing of the wound of approximately 1 cm revealed likely extension to the mandible itself means that the infection was likely coming from the bone. (648:10-19.) Inferior border of the mandible was white without significant bleeding and with a coarse look to the bone with some pitting noted relates to diagnosis of stage 0 ONJ in that the bone itself is not looking normal. (648:20-649:1.) |
| Hellstein and Exh. 3.0049 | Dr. Elwell December 4, 2003, record. (Ex. 3.0049, p. 60) Dr. Elwell has been unable to find why she's infected. (649:2-6). Also in December 2003, Dr. Elwell notes a slight soap bubble honey comb appearance. This is almost interchangeable with moth eaten. (649:9-22.) |
| Hellstein | Exposed bone was not evident in the records until some time in late 2005. But this is one of the peculiarities of the problem. It is so long acting and so long lasting. Dr. Elwell was doing everything he could but it didn't work and eventually she had exposed bone that goes to our definition of stage 3 BRONJ. But that doesn't mean the process wasn't going on for much longer. (654:3-23.) |

These records were considered by the Court, expressly, when it denied Defendant's Rule 50(a) motion at trial:

> And viewing the evidence in the light most favorable to the plaintiff, a reasonable jury could find that the jaw problems she suffered before October 2003 was subclinical osteonecrosis of the jaw that later became exposed and developed into Stage 3 ONJ. The radiograph taken before October 2003 described her jaw as having, quote, a moth-eaten, closed quote, appearance consistent with necrosis.
>
> Testimony and medical records here show that the jaw problems have been fairly continuous since 2002 . . . .
>
> I believe that there's enough for the claim to go to the jury; so the motion is denied in all respects.

(1631:2-18.)

Defendant has presented no new evidence or intervening authority showing this Court that it has committed clear error. This Court should deny Defendant's Rule 50(b)

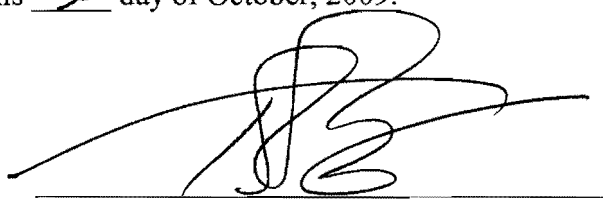
motion.

## CONCLUSION

For the foregoing reasons, this Court should deny Defendant's Rule 50(b) motion.

* * *

RESPECTFULLY SUBMITTED, this 30th day of October, 2009.

BY: 

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**CERTIFICATE OF SERVICE**

I certify that on this 30th day of October, 2009, I served all counsel of record by filing the foregoing pleading using this Court's ECF system, and by mailing a copy of the same by first class U.S. Mail to the following:

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